

## **REMARKS**

Applicant respectfully requests reconsideration of this application in view of the foregoing amendments and the following remarks.

### **I. Status of the Claims**

Upon entry of the amendments, claims 26-28, 31-36, and 38-48 will be pending in the application. Claim 26 is amended, and claims 39-48 are added, to recite specific embodiments. Support for these claims is found throughout the application as filed. For example, the specification and examples relate to compositions comprising a pharmaceutically active agent that consists essentially of (and that consists of) 4-hydroxy tamoxifen.

Applicant respectfully requests entry of these amendments after final because they are believed to place the application in condition for allowance or, at the very least, in better condition for appeal.

### **II. Oath/Declaration**

The Office Action continues to require a declaration setting forth the inventors' "post office" addresses. Applicant notes that the "residence" addresses set forth in the declaration submitted October 19, 2004 are the inventors' post office addresses. Applicant is submitting a supplemental Application Data Sheet to clarify this matter.

### **III. § 103 Rejections**

Claims 26-28, 31-34 and 36 were rejected under 35 U.S.C. § 103(a) for alleged obviousness over Mauvais-Jarvis in view of Gunther. Claim 35 was rejected for alleged obviousness over those same references, further in view of U.S. Patent No. 5,720,963 (Smith). Claim 38 was rejected for alleged obviousness over Mauvais-Jarvis and Gunther, further in view of U.S. Patent No. 6,013,270 (Hargraves). Applicant respectfully traverses these rejections.

The Office Action alleges that someone skilled in the art would have been motivated to use the isopropyl myristate penetration enhancer of Gunther in the percutaneous

composition of Mauvais-Jarvis, because the Mauvais-Jarvis composition comprises progesterone, a steroid hormone, and Gunther teaches fatty acid esters as penetration enhancers for steroid hormones. Without acquiescing to this reasoning, Applicant notes that it does not support the obviousness of the instant claims.

The instant claims recite pharmaceutical compositions for percutaneous administration comprising a pharmaceutically active agent and at least one fatty acid ester penetration enhancer, wherein the pharmaceutically active agent consists essentially of 4-hydroxy tamoxifen (claims 26-28, 31-36, and 38) or wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen (claims 39-48). As set forth in MPEP § 2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention” (emphasis in original). According to Mauvais-Jarvis, column 2, lines 38-50, compositions comprising 4-hydroxy tamoxifen and progesterone exhibit “complementary and synergistic actions.” Thus, it should be apparent to the Examiner that including progesterone in the instantly recited compositions would “materially change the characteristics of applicant’s invention” and, therefore, that compositions comprising progesterone are excluded from the instant claims.

So, even if a skilled artisan were motivated by Gunther to modify Mauvais-Jarvis’ steroid-containing compositions to include a fatty acid ester, they would not arrive at compositions of the present invention. This is because the instant claims exclude compositions such as those described in Mauvais-Jarvis, which include both 4-hydroxy tamoxifen and progesterone as pharmaceutically active agents.

Moreover, as explained in Applicant’s previous response, Gunther’s teachings that fatty acid esters are useful as penetration enhancers for steroids does not suggest the use of fatty acid esters as penetration enhancers for 4-hydroxy tamoxifen. The ability of a particular penetration enhancer to be effective for a particular active agent in a particular formulation is unpredictable. Moreover, structural differences between 4-hydroxy tamoxifen and the steroids of Gunther are such that they would not lead someone skilled in the art to expect a

compound that is effective as a penetration enhancer for one also to be effective as a penetration enhancer for the other.

For at least the foregoing reasons, the obviousness rejection of claims 26-28, 31-34 and 36 should be withdrawn.

The rejections of claims 35 and 38 rely on Gunther and Mauvais-Jarvis to suggest the compositions recited in claim 26, from which these claims depend. Because the combination of Gunther and Mauvais-Jarvis does not suggest the compositions recited in claim 26, and because neither Smith nor Hargraves remedy the deficiencies of the primary references, the obviousness rejections of claims 35 and 38 likewise should be withdrawn.

**IV. Concluding Remarks**

Applicant believes that this application is in allowable condition, and respectfully requests an early indication to this effect. If the Examiner believes that any issue requires further consideration, she is invited to contact the undersigned directly.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 CFR §§ 1.16-1.17, and credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to deposit account. If any extensions of time are needed for timely acceptance of concurrently submitted papers, Applicants hereby petition for such extension, under 37 CFR §1.136, and authorize payment of any extension fees from the same account.

Respectfully submitted,

Date January 3, 2007

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